

(the obturator) of Leiboff with the tube of Majlessi for easily grasping the spherical bulbous enlargement 26 that is about 0.25 inches (or from about 0.25 inches to about 0.75 inches)" (Office Action at page 3).

The obturator 34 of Leiboff has a significantly different purpose than the colonic irrigation tube or drain tube of Majlessi and in view thereof, one skilled in the art would not have considered modifying the obturator of Leiboff to have a larger, graspable front end in view of Majlessi. Thus, there would not be a guidewire with a bulbous enlargement having a diameter of at least about 0.25 inches as set forth in independent claims 1 and 23. (Note that this argument is also applicable to dependent claims 13 and 18 which recite that the guidewire has a bulbous enlargement having a diameter of about 0.25 inches to about 0.75 inches.)

The purpose of the obturator 34 in Leiboff is to facilitate insertion of a drain tube 22a, which is placed over the obturator 34, into the tract portion since it provides a rounded front surface and the drain tube 22a has an opening in its front surface at distal end 33 which would hinder its solitary insertion into the tract portion. The enlarged front end of the obturator 34 is not grasped during use and once the drain tube 22a is in place, the obturator 34 is removed (see col. 16, lines 47-52, "After surgical anesthesia has been induced and with the patient in a low lithotomy position on the operating table, the distal portion of either the single or double side arm drain tube is inserted into the point of access to the portion of the gastrointestinal tract being cleansed with the aid of an obturator *which is then removed.*", emphasis added). The obturator 34 also does not allow for any fluid flow therethrough.

The purpose of the drain tube 10 in Majlessi is to allow fluid flow through tubes 12, 16 formed therein. Drain tube 10 includes

an enlarged front end 26 which enables the drain tube 10 to be grasped and positioned where desired to optimize the fluid flow into and out of the tube 10 (see col. 4, lines 20-27). Apertures 24 are formed in the enlarged front end 26, at its tip and along its sides, and fluid flows into the tube 12 through apertures 24 (see Fig. 1).

Since the drain tube of Majlessi is inherently designed to allow fluid flow therethrough from an enlarged, positionable front end, there is no reason why one skilled in the art would even consider enlarging the solid tip of the obturator 34 of Leiboff to the dimensions of the enlarged front end of Majlessi, much less the obviousness of such a modification. The obturator 34 of Leiboff is not an irrigating tube as is the drain tube of Majlessi, and does not allow for any fluid flow therethrough, as does the drain tube of Majlessi.

Moreover, the obturator 34 is not designed to be grasped and indeed, there is no reason why one would want to grasp the obturator in the manner in which it is used in Leiboff. In Leiboff, the obturator 34 is removed after the drain tube 22a is in place and therefore is not present when fluid is flowing through the drain tube 22a. Its absence during use of the drain tube would preclude any need to make its front end enlarged to enable it to be easily grasped and positioned to optimize fluid flow therethrough.

It is for this reason that the front end of the drain tube of Majlessi is enlarged. Since the obturator 34 of Leiboff is not used as a drain tube, the desirability of enlarging the front end of a drain tube to facilitate easier grasping and positioning as in Majlessi, is completely inapplicable to Leiboff. Neither Leiboff nor Majlessi teach or suggest providing an obturator which can be grasped by a surgeon during insertion of a drain tube. Thus, the cited prior art lacks a teaching to provide an obturator with an

enlarged front end since Majlessi, at most, can only teach providing a drain tube which is designed to be grasped with an enlarged front end to facilitate easier grasping. This teaching of Majlessi is not applicable to an instrument which is not a drain tube and is not otherwise designed to be grasped.

In summary, there is no bona fide reason in the prior art of record or proposed by the Examiner why one skilled in the art would look at the drain tube of Majlessi and consider enlarging the front end of the obturator of Leiboff.

Novel Features Argument

The cited prior art does not disclose, teach or suggest all of the features of claims 7-22, 29 and 30.

Claim 7 is directed to a method for irrigating a body cavity including three steps which are performed in a specific order, noting the presence of the word "then" between the successively recited steps in order to establish this particular order. The first step is pushing a guidewire having a bulbous enlargement at a distal end into the body cavity. The second step is sliding an irrigating tube over or along the guidewire, the irrigating tube having a distal end, a passage and an opening at or near the distal end which communicates with the passage. The third step is directing fluid through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire such that the fluid flows from the passage out of the opening at or near the distal end of the irrigating tube into the body cavity to irrigate the body cavity.

Similarly, claim 15 is directed to a colonic irrigation device including a guidewire having a bulbous enlargement at a distal end, and an irrigating tube movable relative to and over or along the guidewire and including a distal end, a passage and an opening at or near the distal end which communicates with the passage. The

guidewire is guidable into the colon and then the irrigating tube is moved over or along the guidewire into the colon. The irrigating device also includes means for providing a flow of fluid through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire such that the fluid flows from the fluid flow providing means into the passage, through the passage and then from the passage out of the opening at or near the distal end of the irrigating tube into the colon to irrigate the colon.

The features of claims 7 and 15 are described in the specification at, for example, page 7, lines 6-9 and page 10, lines 7-22.

Leiboff describes various methods and apparatus for intestinal irrigation, in some of which an obturator 34 is used (which the Examiner is considering to correspond to the guidewire in the present claimed invention). Specifically, the obturator 34 is used to insert the drain tube 22a into the tract portion being cleansed (see col. 12, lines 1-12, "The distal end 33 of drain tube 22a is formed with rounded edges foratraumatic insertion of the tube into the point of access to the tract portion being cleansed, such as the anus, with the aid of an obturator 34 (FIG. 2)..."). The obturator 34 is inserted through a channel in the drain tube 22a until its tip protrudes from the distal end 33, and then with this configuration, the drain tube 22a and obturator 34 are inserted into the tract portion with the obturator 34 facilitating easier insertion of the drain tube 22a in view of its rounded front surface. Once the drain tube 22a has been inserted into the tract portion being cleansed, the obturator 34 is removed. After removal of the obturator 34, fluid is directed through the drain tube 22a.

In contrast to the embodiment of the invention set forth in claim 7, the obturator 34 is not pushed into the body cavity and

then the drain tube slid over or along the guidewire and then fluid directed through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire.
Rather, in Leiboff the obturator is pushed into the body cavity simultaneous with the drain tube and is removed before fluid is directed through the drain tube.

Similarly, Leiboff does not disclose means for providing a flow of fluid through a passage defined by the irrigating tube "while said irrigating tube is situated over or along said guidewire", as set forth in claim 15.

Majlessi and Stevens do not disclose any method for irrigating a body cavity including a guidewire and a drain tube, and therefore cannot support the obviousness of modifying Leiboff to provide a method for irrigating a body cavity including the steps recited in claim 7 in the specified order or to provide a colonic irrigation device including the features recited in claim 15.

Since Leiboff, Stevens and Majlessi taken individually and in combination do not disclose, teach or suggest all of the features of the embodiments of the invention set forth in independent claims 7 and 15, and claims 7 and 15 should be patentable over the prior art of record.

For the same reasons that claims 7 and 15 should be patentable over the prior art of record, claims 8-14, 16-22, 29 and 30, which depend from claim 7 or claim 15, should also be patentable over the prior art of record. Furthermore, the cited prior art does not disclose all of the features of these dependent claims. For example, with respect to claims 29 and 30, the cited prior art does not disclose that the passage through which fluid is directed while the irrigating tube is situated over or along the guidewire has an inner boundary defined by an outer surface of the shaft and an outer boundary defined by an inner surface of the irrigating tube.

U.S. patent application Ser. No. 10/702,303
Response to Office Action dated Feb. 19. 2008
Response dated Jun. 19, 2008

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 1-30 have been overcome and should be withdrawn and that the present application is now in condition for allowance.

Contact Authorization

The Examiner is invited to contact the undersigned after consideration of this response if prosecution of the application can be advanced telephonically.

Petition for Extension

Applicant hereby petitions for a one-month extension of time to extend the time for response to the Office Action dated February 18, 2008 for one month from May 18, 2008 to June 18, 2008. Payment of the petition fee is being made by credit card upon submission of this Amendment. If any additional fees are necessary for entry of this Amendment, authorization is hereby given to charge any such fees to Deposit Account No. 50-1268.

An early and favorable action on the merits of the invention is earnestly solicited.

Respectfully submitted,

/Brian Roffe/

Attorney for Applicant
Brian Roffe
Reg. No. 35,336

Law Office of Brian Roffe
11 Sunrise Plaza, Suite 303
Valley Stream, New York 11580-6111
Tel. No. (516) 256-5636
Fax No. (516) 256-5638